K092103

510(k) Summary

OCT - 9 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date: May. 11, 2009

1. Company and Correspondent making the submission:

Name – Vatach Co., Ltd.
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Contact – Mr. Dong-Taek, Oh
Internet – http://www.vatech.co.kr

2. Device :

Trade/proprietary name	: ESX
Common Name	: Dental Extraoral Source X-ray System
Classification Name	: Unit, X-ray, Extraoral With Timer

3. Predicate Device :

Manufacturer	: Sirona Dental Systems GMBH
Device	: Heliodent Vario
510(k) Number	: K000672 (Decision Date - May. 02. 2000)

4. Classifications Names & Citations :

21CFR 872.1800, EHD, Unit, X-ray, Extraoral With Timer, Class2

5. Description :

5.1 General

ESX is an extraoral source dental X-ray system intended for intraoral imaging.
It consists of X-ray generator, X-ray controller, beam limiting device, operation panel and mechanical arm. The X-ray controller allows for accurate exposure control, and an adjustable mechanical arm allows for easy positioning. The system can be used either with conventional film or a digital imaging system.

5.2 Product features

1). Condition of Input

•Rated input voltage : AC 110 / AC 230V

•Guaranteed working voltage

-110V Mode : 100 ~120V / 230V Mode : 210 ~250V

•Possible working voltage

-110V Mode : 90 ~130V / 230V Mode : 190 ~ 250V

•Rated input frequency: 50Hz/60Hz

•Insulation withstanding: below than 1.5KV cap for more than one minute between first test and second test.

2) X-ray Tube

- Tube Voltage : 50 - 65 kVp
- Tube Current : 19 mA (Max)
- Focal spot : 0.8 mm
- Inherence Filtration : 0.8 mm Al
- Total Filtration : 2.0 mm Al

3) High-voltage Generator

- Tube Voltage : 65 kVp(Fixed)
- Tube Current : 5 mA(Fixed)

4) X-Ray Controller : **AutoSet Timer**

- Exposure time: 0.05 ~ 1.5 s

- Beam Limiting (200mm)

5) Beam Limiting Device : Round Type

- Distance between focus and surface : 200 mm
- Output Radiation Field : Round Ø 65 mm
- Weight : 0.1 kg

6. Indication for use :

The ESX is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment of disease of the teeth, jaw and oral structures.

7. Comparison with predicate device :

Vatech Co., Ltd., believes that the ESX is substantially equivalent to the Heliodent Vario of Sirona Dental Systems Gmbh.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory.

9. Conclusion :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Vatech Co., Ltd. concludes that ESX is safe and effective and substantially equivalent to predicate devices as described herein.

10. Vatech Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

VATECH Co., Ltd.
% Mr. Vincent Lee
Product Compliance Officer
E-WOO Technologies USA, Inc.
256 North Sam Houston Pkwy E. #115
HOUSTON TX 77060

OCT – 9 2009

Re: K092103
Trade/Device Name: Dental Extraoral Source X-ray System (ESX)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: May 11, 2009
Received: July 14, 2009

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K092103

Device Name: ESX

Classification: Unit, X-ray, Extraoral With Timer

Indications for Use:

The ESX is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment of disease of the teeth, jaw and oral structures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092103